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Before the U.S. House of Representatives
Committee on Agriculture
July 24, 2003

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Good Morning, Mr. Chairman, members of the Committee, thank you for the opportunity to appear before you today. I am Dr. Alfred Munzer. I am an American Lung Association volunteer and had the privilege of serving as President of the national organization in 1993-1994. I am also head of Pulmonary Medicine at Washington Adventist Hospital in Takoma Park, Maryland.

The American Lung Association was founded in 1904 to combat the major public health crisis of that day -- tuberculosis. For over 40 years we have worked to combat the major public health crisis of the second half of the twentieth century and sadly into the 21st – tobacco.

Tobacco is a killer. Each day in my practice I see the victims and their families, men and women, mothers and fathers with diseases like emphysema, chronic bronchitis, cancer and heart disease. I have been a physician since 1968. With today's technology and pharmaceutical interventions I can help patients in ways I could only imagine as a young intern in Brooklyn. But, then as now, I can't undo the damage that smoking does to the lungs.

The evidence that smoking kills is overwhelming. Over 440,000 Americans die from diseases directly related to cigarette smoking each year. Smoking is responsible for one in five U.S. deaths. About half of all regular cigarette smokers will eventually be killed by their addiction.

The economic costs are astronomical. Smoking-related diseases are conservatively estimated to cost the United States at least $150 billion each year—in direct health care costs (hospital care, physician and other professional care, and medications) and lost productivity. These estimates do *not* include such smoking-related conditions as burns suffered in smoking-related fires, low birthweight and prematurity related to smoking by pregnant women, or illnesses traceable to secondhand exposure to smoke.

Smoking is directly responsible for 87 percent of lung cancer and causes most emphysema and chronic bronchitis. Smoking is also a major factor in coronary heart disease and stroke, causes malignancies in other parts of the body, including the esophagus, has been associated with other cancers of the gastrointestinal tract, urinary tract, and cervix; and has been linked to a variety of other conditions and disorders, including slowed wound healing, impotence, infertility, peptic ulcer disease, ectopic pregnancy, and bone-density deficits in women.

Smoking in pregnancy accounts for an estimated 20 to 30 percent of low-birthweight babies, up to 14 percent of preterm deliveries, and 10 percent of all infant deaths. One in 10 preterm infants suffer from respiratory distress syndrome. Smoking presents risks to the fetus throughout pregnancy. Studies also have found maternal smoking during pregnancy associated with childhood lags in physical growth. Researchers have found that the most significant impact of prenatal smoking on physical growth—influence on birthweight—occurs during the third trimester, the last three months of pregnancy.

Smoking by parents has also been associated with a wide range of adverse effects in their children, including exacerbation of asthma, increased frequency of colds and ear infections, and sudden infant death syndrome. Exposure to secondhand smoke increases the severity and

frequency of asthma episodes; in the United States, 200,000 to 1,000,000 children with asthma have experienced aggravated symptoms due to secondhand smoke. Exposure to secondhand smoke also causes 150,000 to 300,000 lower respiratory tract infections (pneumonia and bronchitis) annually in children 18 months and younger; these infections result in 7,500 to 15,000 hospitalizations each year. In addition, secondhand smoke exposure causes a buildup of fluid in the middle ear, resulting in 700,000 to 1.6 million physician office visits. Middle ear infections are the most common cause of childhood operations and of childhood hearing loss. A California Environmental Protection Agency study estimated 1,900 to 2,700 sudden infant death syndrome (SIDS) deaths annually are associated with secondhand smoke exposure.

Secondhand smoke also can be lethal to adults. Secondhand smoke is estimated to cause 3,000 lung cancer deaths and 35,000 heart disease deaths each year. The Environmental Protection Agency (EPA) has classified secondhand smoke as a known human (Group A) carcinogen (cause of cancer).

Ninety percent of adults who smoke started by the age of 21, and half of them became regular smokers by their eighteenth birthday. An estimated 4.5 million adolescents smoke, with 2,000 teens ages 11-17 becoming established smokers each day. One third of these will die from a disease caused by smoking.

Current cigarette smoking among high school students is beginning to decline after increasing throughout the first half of the 1990s. In 2001, 28.5 percent of high school students currently smoke cigarettes, down from 36.4 percent in 1997 and 34.8 percent in 1999. Lifetime cigarette use among high school students is 63.9 percent, down from 70.4 percent in 1999. Current frequent smoking, defined as smoking on at least 20 of the 30 days preceding the survey, decreased from 16.8 percent in 1999 to 13.8 percent in 2001.

In summary, smoking kills. Yet what is driving today's hearing, and I recognize the limitations of this committee's jurisdiction, is not public health, not preventing our children from becoming addicted but "tobacco quota buyout and surrounding issues." Mr. Chairman, with all due respect, the congressional priority with respect to tobacco continues to be misplaced.

Earlier this year, the Subcommittee on Cessation of the Interagency Committee on Smoking and Health, a federal panel of experts convened by Health and Human Services Secretary Thompson that included a former Surgeon General and Dr. Seffrin of the American Cancer Society, proposed a bold set of recommendations on how best to promote tobacco use cessation and identify specific action steps. The panel's goals were to reduce the prevalence of tobacco use by 10 percent, prevent 3 million deaths, help 5 million smokers quit within the first year and address disparities. The interagency panel chaired by current Surgeon General Richard Carmona endorsed the recommendations. The plan included federal initiatives and public private partnerships. The key federal elements are:

- A national tobacco quitline network
- A national paid media campaign
- Coverage for evidence-based tobacco cessation counseling and medications for all federal beneficiaries and in all federally-funded healthcare programs

- Invest in a new, broad, and balanced research agenda
- Educate clinicians-in-training and practicing clinicians
- Establish a Smokers' Health Fund – by increasing the Federal Excise Tax on cigarettes by $2.00 per pack

The administration shot down the proposal immediately and rejected the opportunity to prevent 6 million children from smoking. The plan would help 4.6 million adults quit in the first year. Also the tax increase would raise $28 billion in federal revenue. A significant opportunity to have a dramatic impact on public health was lost.

For over 20 years, the American Lung Association has advocated for strong federal regulatory oversight over tobacco products. We support adequately funded, full Food and Drug Administration regulatory authority over the manufacture, sale, distribution, labeling, marketing and promotion of tobacco. We strongly support legislation like the balanced, bipartisan, compromise bills introduced in the 107th Congress (HR 1043, and HR 1044) by Mr. Waxman, HR 1097 by Mr. Ganske as well as S. 2626 sponsored by Senator Kennedy and Senator DeWine. These bills provide the FDA with the authority necessary to protect public health. The House bills regulate tobacco under the Food Drug and Cosmetic Act as a drug and device, while the Senate approach creates a new chapter in the law for tobacco. Both approaches provide the necessary authority. We strongly oppose the Philip Morris approach to FDA encompassed in Mr. McIntyre's HR 140. Effective FDA legislation must address the following:

- **Youth Access and Marketing.** Legislation should grant FDA authority regarding the sale and distribution of tobacco products, including access, advertising, and promotion.

- **Adoption of Youth Access and Marketing Restrictions of the 1996 Rule to Help Reduce Youth Tobacco Use.** Legislation should incorporate the substance of the youth access and youth marketing restrictions adopted by the FDA so that the agency would not need to go through a new rulemaking process to implement them.

- **Health Information Disclosure.** Legislation should entitle FDA to receive all documents and information in the tobacco industry's possession relating to health effects of all tobacco products, nicotine and its effects on the body, addiction, marketing to children and its effects, and such other information that the HHS Secretary deems necessary to enable the FDA to protect the public health.

- **"Public Health" Standard.** The existing FDA standard for approving drugs and devices is whether there is a "reasonable assurance that a product is safe and effective." Because there is no such thing as a safe cigarette, legislation should create a new "protection of the public health" standard for all tobacco products that refers to reducing health risks to the American public. This standard would require consideration of whether a product change or new rule will reduce or increase tobacco use, including increasing the number of new users or decreasing the number who quit.

- **Disclosure of Ingredients.** Legislation should grant FDA authority to require the tobacco industry to provide a complete list of all tobacco ingredients and additives, by brand and by

quantity, and the authority to require that this information be given to the public in a manner that does not disclose legitimate trade secrets. It should further provide FDA with authority to regulate the use of any ingredient or additive that is harmful or which contributes to the harmfulness of the product. Also, the burden should be placed on tobacco manufacturers to demonstrate that each ingredient and additive is safe in the quantity used under the conditions of intended use.

- **Health Warnings.** Legislation should grant FDA authority over health warnings on tobacco product packages and advertisements, including the power to revise and add health warnings and to alter their format, including, but not limited to changing their size, location, and color.

- **Authority to Reduce or Eliminate Harmful Components.** Legislation should grant FDA the authority to evaluate scientifically, and then through a rulemaking process, to decide whether to reduce or, where appropriate, eliminate the harmful and addictive components of all tobacco products in order to protect the public health.

- **Health Claims and "Reduced Risk" Products.** Legislation should grant FDA authority to encourage the development of products that reduce consumer health risks or serve as less harmful alternatives and the authority to evaluate scientifically whether new products are actually "less harmful." It also should provide FDA authority to prohibit or restrict directly or indirectly made: (1) unsubstantiated health claims; and (2) health claims that discourage people from quitting or encourage them to start using tobacco.

- **Preemption.** FDA authority should pre-empt state and local authority over tobacco products only to the extent that FDA authority with regard to other products it regulates is preemptive.

- **FDA Authority over Tobacco Farms or Tobacco Growers.** Legislation should make clear that FDA would not have authority over tobacco farms or tobacco growing.

- **Routine Regulatory and Procedural Fairness.** Legislation should subject tobacco products to the same standards or procedures that are applied to other FDA-regulated "drugs" or "devices."

There is much work to be done to help addicted smokers quit, prevent children from becoming addicted and to provide the needed regulatory oversight over tobacco products and eliminate exposure to secondhand smoke. Our nation needs to address these pressing public health issues. This is where policy makers at the local, state and national level should focus their attention.

With respect to a potential tobacco buyout, the American Lung Association supports economic transition assistance for tobacco growers, workers and their communities. But, the federal taxpayer should not finance any program that supports tobacco growth, production, marketing, administrative costs or any other purpose that promotes or facilitates tobacco use, either in the United States or abroad. We have empathy for the economic disruption facing those dependent on tobacco growing. It is appropriate to help tobacco growers and workers exit the tobacco business. It is wrong for the federal taxpayer to subsidize tobacco.

To those who say that the United States tobacco grower's future lies in the export market, we strongly disagree. It is immoral for the United States to export cancer, emphysema and heart disease.

It is time to recognize that the sun is setting on tobacco. Yes, we have a long road ahead. Tobacco remains a global scourge. Tobacco still kills nearly 5 million people annually around the world. But, in the United States, adult smoking prevalence rates have declined significantly since the landmark 1964 Surgeon General's report. Over 40 nations have signed the World Health Organizations' first public health treaty, the Framework Convention on Tobacco Control. The progress is being made, despite the best efforts of the global tobacco companies to addict children in Asia, Africa, Eastern Europe and Central and South America, the nations of the world are stepping forward and saying "no" to addiction, disease, disability and death for their citizens, "no" to big tobacco and "yes" to good public health practice and "yes" to tobacco control. We hope President Bush will sign this landmark public health treaty soon and send it to the Senate for ratification.

To reiterate and be clear, there should not be any subsidy for continuing to grow tobacco. Buyout legislation should not be used as catalyst to pass weak and ineffective FDA legislation. The American Lung Association supports economic transition assistance for tobacco growers, workers and communities but tobacco production should be phased out.

Thank you.